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EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	PAPER NUMBER
3739	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/660,840	REMIJAN ET AL.	
	Examiner	Art Unit	
	John P. Leubecker	3739	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 39-80* is/are pending in the application.

4a) Of the above claim(s) *19-21,34,40-50,52-58 and 70-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,22-33,35,39,51 and 59-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 5, 6, 9, 12, 15, 17, 18, 22-31, 33, 35, 39, 51 and 59-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Allred, III (U.S. Pat. 4,854,302) and further in view of Kurtzer (U.S. Pat. 5,168,863) and Santangelo et al. (U.S. Pat. 4,610,242).

As to claims 1, 28 and 51, Siegmund et al. discloses a probe including an optical waveguide (1) having a light absorbing layer (7), a concentric fiberoptic illumination channel (25, col.4, lines 26-28), a handle (3,27) removably attached (via threads 39, such coupling anticipating first and second coupling elements) to the probe, an optical lens element (5, which can be a positive lens, negative lens or lens system (col.4, lines 9-10), such lens system would

encompass a first and second lens; in addition note Figs. 8a-8c and 9) coupled to the distal end of the waveguide, an optical relay (17) mounted in the handle (Fig.1) and optically coupled to a proximal end of the waveguide, and an imaging device (CCD camera) mounted in the handle at a proximal end of the optical relay. The fiberoptic illumination channel comprises an outer sheath (37) and an inner sheath (the metallic, paint or resin layer, col.3, line 62 to col.4, line 8).

Siegmund et al. fails to specify the length and diameter of optical waveguide. However, analogous miniature endoscopes (note Allred, III, Figure 2, col. 4, lines 28-34) are known to include an optical waveguide with a diameter of 2 mm or less and a length of somewhere between 3.3 cm and 11 cm[1]. Since Siegmund et al. fails to teach any particular length and diameter, it would have been obvious to one of ordinary skill in the art to have made the waveguide any desired diameter and length to meet the particular requirements for a certain procedure, and specifically, any length and diameter contemplated in the prior art, since such contemplation suggests a particular need or use for those dimensions in the prior art.

Siegmund et al. further fails to disclose a sterile disposable sheath attached to the probe and extending over the handle. However, Kurtzer teaches an analogous endoscope having such sheath (20). It would have been obvious to one of ordinary skill in the art to have provided a sheath over the handle of Siegmund et al. to provide a sterile barrier between the handle/camera and the patient to protect the patient from any contamination from elements of the device which are normally handle by the surgeon and to protect the handle/camera from contamination from the patient (e.g., fluids, bacteria).

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[1] The probe sleeve (18) is about 3.3 cm in length and the main housing (12) about 7.5 cm in length. Since the optical waveguide (24) extends slightly into the main housing (note proximal end 42, Fig.2), it would have a length of somewhere between 3.3cm and the overall length of about 11 cm.

Siegmund et al. discloses the endoscope as claimed but further fails to disclose a separate cannula that receives the distal end of the probe such that the outer sheath (37) slides within the cannula and that the cannula has a locking mechanism at a proximal end that attaches to the probe. Santangelo et al. demonstrates what is conventional in the endoscope art in that endoscopes are known to be used with a cannula and trocar (stylet) for providing an entry site for the endoscope into the body through the skin (col.1, lines 14-35). Santengelo et al. teaches such cannula/trocar combination (Figs.2,3) wherein the cannula (18,20, Fig.1) includes a locking mechanism (30 in Fig.1 or 31'/36' in Fig.11) at a proximal end to attach to a hub (22) of the endoscope. In addition, Santengelo et al. further teaches a fluid delivery port (51,col.4, lines 62-64) on the cannula for introducing or aspirating fluid through the cannula. It would have been obvious to one of ordinary skill in the endoscope art to have used the endoscope of Siegmund et al. with the cannula/trocar arrangement of Santangelo et al., if not for the fact that such combination of devices are known and used, for the purpose of providing an entry site into the patient (col.1, lines 29-30), protecting the distal end of the endoscope (col.1, lines 41-45) and allowing quick and easily insertion of the endoscope to a proper axial and rotational position (col.1, line 69 to col.2, line 6).

Clearly a diameter of less than 2 mm, as taught by Allred, III would encompass the diameters of claims 2 and 3. As to claim 5, 6, 30 and 31, the waveguide of Siegmund et al. comprises a high-index glass rod of a refractive index greater than 1 (which includes 1.6). As to claim 9, note col.4, lines 3-8. As to claim 12, the outer sheath (37) comprises a metal (col.4, lines 23-25). As to claims 18 and 68, the cannula tip (21) forms a needle (note tapered pointed end 21, Fig.1of Santangelo). As to claims 17, 22 and 39, an image from a CCD camera is

inherently viewed on a display. As to claims 23 and 36, note that optical fibers (25) are optically coupled to a light source in the handle (note coupling point 43) via fiber optic connector (41). As to claim 24, note coupling 39. As to claims 26, 63 and 64, note in Kurtzer that the sterile barrier (20) is attached to the probe via a disposable probe element (13, Fig.6, col..5, lines 37-59) As to claim 59, note optical fibers (41). As to claim 60, note ring of optical fibers (25). As to claims 61 and 62, note col.4, line 27. As to claim 67, note col.6, lines 17-26 regarding a locking mechanism (70) and further note the locking mechanism of Santangelo et al. As to claim 69, the trocar (60, Fig.3) constitutes a stylet.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III, Kurtzer and Santangelo et al., as described above, and further in view of Woodard et al. (U.S. Pat. 5,947,958).

Although the different distal tip configurations (71,72, Figs. 8b,8c) of Siegmund et al. provide dispersive properties and could be considered as a "ring", Woodard et al. explicitly teach that, in an alternative to forming the tip, that other dispersive elements including lenses and refractive gradients could be used (col.5, lines 39-44). Thus, it would be obvious to one of ordinary skill in the art to have used a separate dispersive element in the device of Siegmund et al. as an obvious design alternative for dispersing the illumination light.

5. Claims 7, 10, 13, 14, 16 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III, Kurtzer and Santangelo et al.

As to claims 7 and 10, Siegmund et al. fails to specify the thickness of the light absorbing layer and the wall thickness of the illumination channel. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of these layers (Applicant discloses the claimed ranges simply as preferred), the choice of such thicknesses would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Since miniaturization is a key design consideration in the non-invasiveness of endoscopic devices and thicknesses in the claimed ranges are not extraordinary in the art, such claimed ranges would be considered obvious and desirable.

As to claim 13, Siegmund et al. explicitly teaches that the outer sheath can be made from metals or plastics (col.5, lines 2-3) but fails to specify polyamide. If not inherently encompassed by "plastics", Siegmund's teaching would prompt one of ordinary skill in the art to draw from common knowledge. Polyamide is a well known plastic material. It would therefore be obvious to one of ordinary skill in the art to have used polyamide. Evidence that polyamide is a well known plastic material will be provided only if Applicant disagrees on record to such notice.

As to claim 14, Siegmund et al. fails to mention the thickness of the outer sheath. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of the sheath (Applicant discloses the claimed ranges simply as preferred), the choice of such thickness would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to

attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Since miniaturization is a key design consideration in the non-invasiveness of endoscopic devices and the claimed is not extraordinary in the art, such claimed thickness would be considered obvious.

As to claim 16, Siegmund et al. fails to disclose the material of the lens. Both glass and plastic lenses are notoriously well known in the art. Either can be used for the same purposes and both have advantages and disadvantages. It would have been obvious to one of ordinary skill in the art to have used plastic for the material of the lens of Siegmund et al. as a matter of design choice.

As to claim 32, Siegmund et al. fails to disclose the specific properties of the high index of refraction glass rod (i.e., that it is an F2 or F7 glass). If not inherently encompassed by "high index of refraction glass", Siegmund's teaching would prompt one of ordinary skill in the art to draw from common knowledge. F2 and F7 glasses are well known types of glass. It would have therefore be obvious to one of ordinary skill in the art to have used well known types of glass such as F2 and F7 glass. Evidence that these are well known types of glass will be provided only if Applicant disagrees on record to such notice.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III, Kurtzer and Santangelo et al., as described above, and further in view of Eastman (U.S. Pat. 5,319,731).

Siegmund et al. disclose the device as described above wherein the light absorbing layer is a hydrogen-fired blackened surface and thus fails to disclose such layer as being comprised of extramural absorption glass. Since such extramural absorption glass is known to provide similar properties (e.g., attenuate stray light) (note Eastman, col.1, lines 46-65 and col.5, lines 35-53), it would have been obvious to the skilled artisan to have used extramural absorption glass for the absorption layer as an obvious design alternative. Use of such absorption glass would simplify the application of the absorbing layer by eliminating the hydrogen-firing process while still providing good image quality.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III, Kurtzer and Santangelo et al. as described above, and further in view of Strack (U.S. Pat. 3,902,880).

Since Siegmund et al., as described above, does not mention any specific optical properties, one of ordinary skill in the art would draw from conventional knowledge in the art when reducing such device to practice. Strack evidences that illumination core materials can have a refractive index of 1.5 to 1.81 (col.3, lines 12-17) with the refractive index of the cladding being lower. The claimed ranges are inherent properties of typically known materials (e.g., glasses, plastics) that have been used for the same purposes (e.g., illumination). Clearly, such specific optical properties would be obvious to one of ordinary skill in the art as they are inherent in the materials that would conventionally be used.

Response to Arguments

8. Applicant's arguments filed November 25, 2008 have been fully considered but they are not persuasive.

The independent claims have been amended to require an additional component, the cannula, that is removably attached to the endoscope. This component, as well as it use with and endoscope, is shown to be conventionally known and used in the art as set forth in the rejections above.

Applicant also argues that it would not be obvious to reduce the size of Siegmund (previous rejection based on Siegmund, Allred and Kurtzer). Again, the Examiner must point out that the position it not that it is obvious to *reduce* the size of the Siegmund device since Siegmund does not specify any particular size.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yoon (U.S. Pat. 4,254,762)—note another cannula system used with an endoscope.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/
Primary Examiner
Art Unit 3739

jpl